2. 510(K) SUMMARY

2.1. GENERAL INFORMATION

Device Common/Usual Generic Name:	ECG Cable
Device Trade Name:	Removable Patient Leads ECG Cable
Applicant's Name and Address:	Boston Scientific Corporation 4100 Hamline Avenue North St. Paul, Minnesota 55112-5798 ERN: 2124215
Product Code/ Regulation Citation:	DSA, Cardiovascular 21 CFR 870.2900
Contact Name and Information:	Melissa Klamerus Regulatory Specialist Phone: 651.582.6771 Fax: 651.582.5134 E-mail: melissa.klamerus@bsci.com
Owner /Operator:	Boston Scientific Corporation One Boston Scientific Place Natick, MA 01760 ERN: 9912058
Manufacturing Facility:	Technical Services for Electronics Inc. (TSE) 2f No. 21 Jian Kang Road Chung Ho City Taiwan ERN: 3008483389

2.2. DEVICE

Removable Patient Leads ECG Cable.

2.3. PREDICATE DEVICE

ECG Patient Cables & Lead Wire System, K771645 (Oct 13, 1977).

2.4. DEVICE DESCRIPTION

The BSC ECG cable, model 6750 is an external device used to transmit ECG signals from electrodes which are affixed to the patient's body to an external BSC programming system that includes an ECG display monitor. Each leadwire clip is attached to ECG patient electrodes. The other end of the leadwire plugs into one end of the trunk cable. The trunk cable then plugs into the BSC programming system.

2.5. INDICATIONS FOR USE

The Removable Patient Leads ECG Cable is used to transmit signals from patient-connected electrodes or transducers to electrocardiograph recorders/monitors for both diagnostic and monitoring purposes.

ECG cables are supplied non-sterile and are not sterilizable; they are reusable devices and are recommended to be used by trained operators in a medical environment. Use is limited by the indications for use of the connected monitoring or diagnostic equipment.

2.6. DEVICE COMPARISON TO PREDICATE

The BSC ECG cable incorporates substantially equivalent design, packaging, fundamental technology, and indications for use as the predicate, ECG Patient Cables & Lead Wire System (K771645). See **Table 2-1** for a comparison between the BSC ECG cable and the predicate device.

Table 2-1: Comparison between BSC ECG cable and predicate device

Characteristic		BSC ECG Cable	Tyco predicate device
Indications for use		*ECG cable is used to transmit signals from patient-connected electrodes or transducers to electrocardiograph recorders/monitors for both diagnostic and monitoring purposes.*	*ECG leadwire is used to transmit signals from patient-connected electrodes or transducers to electrocardiograph recorders/monitors for both diagnostic and monitoring purposes.*
Patient usage		Reusable	Reusable
Sterility		Supplied non-sterile; cannot be sterilized	Supplied non-sterile; cannot be sterilized
Anatomical sites		Attached to electrodes placed at standard specified locations on chest wall and extremities	Attached to electrodes placed at standard specified locations on chest wall and extremities
	Functionality	transmit signals from 5 patient-connected leadwires	transmit signals from 5 patient-connected leadwires

Design/ Appearance	**Number of leadwires** (patient wire)	5	5
	Trunk cable length	120 ± 6 inches	120 ± 6 inches
	Leadwire length (each)	40 ± 1.5 inches	40 ± 1.5 inches
	Connector – Patient end	patient clip	patient clip
	Connector - Monitor end	6 pin DIN AAMI	6 pin DIN AAMI
	Packaging	• outer labeled box • inner labeled bubble pouch • non-sterile	• outer labeled box • inner labeled bubble pouch • non-sterile
	Leadwire colors (ANSI/AAMI/ IEC 60601-2-27)	• white • green • brown • red • black	• white • green • brown • red • black
	Cable Coating Materials	• Polyvinyl Chloride (PVC) • Santoprene • Elastollan	• Polyvinyl Chloride (PVC) • Santoprene

2.7. PERFORMANCE DATA

Electromagnetic compatibility, electrical safety, biocompatibility and bench testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device design meets the performance requirements and performs as intended. No new safety or performance issues were found during device testing.

2.8. CONCLUSION

Based on the indications for use, technological characteristics, and safety and performance testing, the Removable Patient Leads ECG Cable has been shown to be appropriate for its indications for use and is considered to be substantially equivalent to the predicate ECG cable, K771645.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 16, 2013

Boston Scientific
Cardiac Rhythm Management
Ms. Melissa Klamerus
4100 Hamline Avenue North
St. Paul, MN 55112

Re: K132253
Trade/Device Name: Boston Scientific Removable Patient Leads ECG Cable, Model 6750
Regulatory Number: 21 CFR 870.2900
Regulation Name: Patient Transducer and Electrode Cable (including Connector)
Regulatory Class: Class II (Two)
Product Code: DSA
Dated: November 14, 2013
Received: November 15, 2013

Dear Ms. Klamerus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known)

Device Name **Removable Patient Leads ECG Cable**

Indications for Use

The BSC Removable Patient Leads ECG Cable is used to transmit signals from patient-connected electrodes or transducers to electrocardiograph recorders/monitors for both diagnostic and monitoring purposes. ECG cables are supplied non-sterile and are not sterilizable; they are reusable devices and are recommended to be used by trained operators in a medical environment. Use is limited by the indications for use of the connected monitoring or diagnostic equipment.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use____ (Per 21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.12.16 16:21:28 -05'00'